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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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STERNE, KESSLER, GOLDSTEIN & FOX PLLC
1100 NEW YORK AVENUE, N.W.
WASHINGTON, DC 20005

EXAMINER	
FETTEROLF, BRANDON J	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 06/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/826,923	KASIBHATLA ET AL.	
	Examiner	Art Unit	
	Brandon J. Fetterolf, PhD	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) *10-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

The Election filed on April 27, 2006 in response to the Restriction Requirement of April 7, 2006 has been entered. Applicant's election with traverse of Group I, claims 1-9, as specifically drawn to a method of treating, preventing or ameliorating a disease responsive to induction of the caspase cascade in an animal comprising administering to an animal a compound which specifically binds to a Tail Interacting Protein Related Apoptosis Inducing Protein (TIPRAIL), wherein said compound induces activation of the caspase cascade has been acknowledged. However, because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the restriction requirement is deemed to be proper and is made FINAL.

Claims 1-32 are currently pending

Claims 10-32 are withdrawn from consideration as being drawn to non-elected inventions.

Claims 1-9 are currently under consideration.

Species Election

The Election filed on April 27, 2006 in response to the Species Requirement of April 7, 2006 has been entered. Applicant's election of breast carcinomas for prosecution on the merits is acknowledged and appreciated. However, the requirement for an election of a species has been withdrawn upon further review and reconsideration.

Information Disclosure Statement

The Information Disclosure Statements filed on 7/19/2005 and 2/21/2006 are acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner. A signed copy of the IDS is attached hereto.

Specification

The disclosure is objected to because of the following informalities:

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code, see for example page 43. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-9 are rejected as vague and indefinite for reciting the term Tail Interacting Protein Related Apoptosis Inducing Protein (TIPRAIP) as the sole means of identifying the claimed molecule. The use of laboratory designations only to identify a particular molecule renders the claims indefinite because different laboratories may use the same laboratory designations to define completely distinct molecules. The rejection can be obviated by amending the claims to specifically and uniquely identify Tail Interacting Protein Related Apoptosis Inducing Protein (TIPRAIP), for example, by SEQ ID NO. and function of Tail Interacting Protein Related Apoptosis Inducing Protein (TIPRAIP).

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant case, the claims are inclusive of a genus of compounds that specifically bind to a genus Tail Interacting Protein Related Apoptosis Inducing Protein (TIPRAIP) with the proviso that the

compound is not 3-(4-azidophenyl)-5-(3-chlorothiophen-2-yl)-[1,2,4]-oxidiazole or a substituted 3-aryl-5-aryl-[1,2,4]-oxidiazole. Therefore, the claims encompass a genus of compounds and proteins defined solely by their principal biological property, which is simply a wish to know the identity of any material with that biological property. However, the speciation only reasonably conveys twelve species of Tail Interacting Protein Related Apoptosis Inducing Protein's (TIPRAIP's) and appears to be silent on the structural features common to any "compound" other than a 3-(4-azidophenyl)-5-(3-chlorothiophen-2-yl)-[1,2,4]-oxidiazole or a substituted 3-aryl-5-aryl-[1,2,4]-oxidiazole which specifically binds to a genus Tail Interacting Protein Related Apoptosis Inducing Protein (TIPRAIP).

The Written Description Guidelines for examination of patent applications indicates, "the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical characteristics and/or other chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show applicant was in possession of the claimed genus." (Federal register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, see especially page 1106 column 3) and (see MPEP 2164).

The specification teaches (page 12, paragraph 0039) that Tail Interacting Protein Related Apoptosis Inducing Protein and "TIPRAIP" refer to the amino acid sequence of SEQ ID NO: 7 and its mutant, homologs, derivative and fragments which affect apoptosis upon binding a 3-(4-azidophenyl)-5-(3-chlorothiophen-2-yl)-[1,2,4]-oxidiazole or a substituted 3-aryl-5-aryl-[1,2,4]-oxidiazole. Specifically, the specification teaches that Tail Interacting Protein Related Apoptosis Inducing Proteins include, but are not limited to, Cargo selection protein (mannose 6 phosphate receptor binding pr) [Homo sapiens] (SEQ ID NO.:1) (NCBI Accession No. XP.sub.--012862); Cargo selection protein (mannose 6 phosphate receptor binding pr) [Homo sapiens] (SEQ ID NO.: 2) (NCBI Accession No. NP.sub.--005808); Placental protein 17b1; PP17b1 [Homo sapiens] (SEQ ID NO.: 3) (NCBI Accession No. AAD11622); Placental protein 17a2; PP17a2 [Homo sapiens] (SEQ ID NO.: 4) (NCBI Accession No. AAD11619); Cargo selection protein (mannose 6 phosphate receptor binding protein) [Homo sapiens] (SEQ ID NO.:5) (NCBI Accession No. AAH05818); Cargo selection protein (mannose 6 phosphate receptor binding protein) [Homo sapiens] (SEQ ID NO.: 6) (NCBI Accession No. AAH19278); Cargo selection protein TIP47

[Homo sapiens] (SEQ ID NO.: 7) (NCBI Accession No. AAC39751); Cargo selection protein (mannose 6 phosphate receptor binding protein) [Homo sapiens] (SEQ ID NO.: 8) (NCBI Accession No. AAH07566); Cargo selection protein (mannose 6 phosphate receptor binding protein) [Homo sapiens] (SEQ ID NO.: 9) (NCBI Accession No. AAH01590); Placental protein 17a1; PP17a1 [Homo sapiens] (SEQ ID NO.: 10) (NCBI Accession No. AAD11620); Cargo selection protein TIP47 (47 kDa mannose 6-phosphate receptor-binding protein) (47 kDa MPR-binding protein) (Placental protein 17) [Homo sapiens] (SEQ ID NO.: 11) (NCBI Accession No. O60664); and Sequence 1 from U.S. Pat. No. 5,989,820 [Unknown] (SEQ ID NO.: 12) (NCBI Accession No. AAE37397). Regarding the compounds which bind specifically to a Tail Interacting Protein Related Apoptosis Inducing Protein (TIPRAIP), the specification teaches a screening assay which can be used to identify compounds that activate the caspase cascade (page 84, E, page 99, IX and 100, X)), as well as a rational drug design using TIRPAIP structure (page 98, VIII). Moreover, the specification provides a plethora of substituted 3-aryl-5-aryl-[1,2,4]-oxidiazole derivatives (beginning on page 16, paragraph 0052 to page 23, including paragraph 0056). Thus, while the specification reasonably conveys 12 species of TIPRAIP's, the specification does not appear to be commensurate with the full scope of compounds and TIPRAIP's as presently claimed. Accordingly, there is insufficient written description encompassing a "genus of compounds that specifically bind to a genus Tail Interacting Protein Related Apoptosis Inducing Protein (TIPRAIP) with the proviso that the compound is not 3-(4-azidophenyl)-5-(3-chlorothiophen-2-yl)-[1,2,4]-oxidiazole or a substituted 3-aryl-5-aryl-[1,2,4]-oxidiazole" because the relevant identifying characteristics of the genus such as structure or other physical and/or chemical characteristics of a the claimed genus are not set forth in the specification as-filed. A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or by describing structural features common the genus that "constitute a substantial portion of the genus." See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997): "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cNDA, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." The Federal Circuit has recently clarified that a DNA molecule can be adequately described without disclosing its complete structure. See Enzo Biochem,

Inc. V. Gen-Probe Inc., 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002). The Enzo court adopted the standard that the written description requirement can be met by "show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics ....i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. " Id. At 1324, 63 USPQ2d at 1613 (emphasis omitted, bracketed material in original).

The court has since clarified that this standard applies to compounds other than cDNAs. See University of Rochester v. G.D. Searle & Co., Inc., __F.3d__,2004 WL 260813, at *9 (Fed.Cir.Feb. 13, 2004). The instant specification fails to provide sufficient descriptive information, such as definitive structural or functional features that are common to the genus. That is, the specification provides neither a representative number of compounds that specifically bind to a Tail Interacting Protein Related Apoptosis Inducing Protein (TIPRAIP) with the proviso that the compound is not 3-(4-azidophenyl)-5-(3-chlorothiophen-2-yl)-[1,2,4]-oxidiazole or a substituted 3-aryl-5-aryl-[1,2,4]-oxidiazole that encompass the genus of compounds nor does it provide a description of structural features that are common to the compounds. Further, the specification fails to provide a representative number of Tail Interacting Protein Related Apoptosis Inducing Protein's (TIPRAIP) that encompass the genus of proteins along with a description of structural features that are common to the Tail Interacting Protein Related Apoptosis Inducing Protein (TIPRAIP). Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, the disclosure is insufficient to describe the genus. Thus, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe and enable the genus as broadly claimed.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure(s) of the encompassed genus of compounds and proteins, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of

isolation. A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. See, e.g., Fujikawa v. Wattanasin, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996) (a "laundry list" disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not "reasonably lead" those skilled in the art to any particular species). Thus, adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claims 1-9 are further rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating or ameliorating a disease responsive to induction of the cascade in an animal, comprising administering to said animal a compound which specifically binds to a TAIL Interacting Protein Related Apoptosis Inducing Protein (TIPRAIP) with the proviso that said compound is not 3-(4-azidophenyl)-5-(3-chlorothiophen-2-yl)-[1,2,4]-oxidiazole or a substituted 3-aryl-5-aryl-[1,2,4]-oxidiazole, does not reasonably provide enablement for a method of preventing any and/or all diseases including cancer which are responsive to induction of the cascade in an animal, comprising administering to said animal a compound which specifically binds to a TAIL Interacting Protein Related Apoptosis Inducing Protein (TIPRAIP) with the proviso that said compound is not 3-(4-azidophenyl)-5-(3-chlorothiophen-2-yl)-[1,2,4]-oxidiazole or a substituted 3-aryl-5-aryl-[1,2,4]-oxidiazole. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands

states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the nature of the invention, (2) the relative skill of those in the art, (3) the breadth of the claims, (4) the amount or direction or guidance presented, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the state of the prior art, and (8) the predictability or unpredictability of the art.

Although the quantity of experimentation alone is not dispositive in a determination of whether the required experimentation is undue, this factor does play a central role. For example, a very limited quantity of experimentation may be undue in a fledgling art that is unpredictable where no guidance or working examples are provided in the specification and prior art, whereas the same amount of experimentation may not be undue when viewed in light of some guidance or a working example or the experimentation required is in a predictable established art. Conversely, a large quantity of experimentation would require a correspondingly greater quantum of guidance, predictability and skill in the art to overcome classification as undue experimentation. In Wands, the determination that undue experimentation was not required to make the claimed invention was based primarily on the nature of the art, and the probability that the required experimentation would result in successfully obtaining the claimed invention. (Wands, 8 USPQ2d 1406) Thus, a combination of factors which, when viewed together, would provide an artisan of ordinary skill in the art with an expectation of successfully obtaining the claimed invention with additional experimentation would preclude the classification of that experimentation as undue. A combination of Wands factors, which provide a very low likelihood of successfully obtaining the claimed invention with additional experimentation, however, would render the additional experimentation undue.

The nature of the invention

The claims are drawn to a method of treating, preventing or ameliorating a disease responsive to induction of the cascade in an animal, comprising administering to said animal a compound which specifically binds to a TAIL Interacting Protein Related Apoptosis Inducing Protein (TIPRAIP) with the proviso that said compound is not 3-(4-azidophenyl)-5-(3-chlorothiophen-2-yl)-[1,2,4]-oxidiazole or a substituted 3-aryl-5-aryl-[1,2,4]-oxidiazole cancer, wherein the disease includes, but is not limited to, cancer. The invention is in a class of invention which the CAFC has characterized as "the unpredictable arts such as chemistry and biology." Mycogen Plant Sci., Inc. v. Monsanto Co., 243 F.3d 1316, 1330 (Fed. Cir. 2001).

Level of skill in the art

The level of skill in the art is deemed to be high, generally that of a PhD or MD.

The breadth of the claims

Applicants broadly claim a method of treating, preventing or ameliorating any disease responsive to induction of the cascade in an animal, comprising administering to said animal a compound which specifically binds to a TAIL Interacting Protein Related Apoptosis Inducing Protein (TIPRAIP) with the proviso that said compound is not 3-(4-azidophenyl)-5-(3-chlorothiophen-2-yl)-[1,2,4]-oxidiazole or a substituted 3-aryl-5-aryl-[1,2,4]-oxidiazole cancer, wherein the disease includes, but is not limited to, cancer.

Guidance in the specification and Working Examples

The specification teaches that compounds of the present invention can be used in a method of treating, preventing or ameliorating a disease in an animal comprising administering to the animal a composition comprising a compound which binds specifically to an TIPRAIP (page 37, paragraph 0088). The specification further teaches various routes by which the present compounds can be administered, as well as the dosage required for treatment (page 38, paragraph 0091 and page 49, paragraph 0116). Thus, while the specification provides various administration routes and effective dosages for in vivo use, the specification appears to be silent on any working examples showing that the claimed method can be used to prevent any disease responsive to induction of the caspase

cascade in an animal. two prophetic examples to identify Akt inhibitors and inhibit tumor growth in vivo, the specification appears to be silent on any correlation between the in vitro testing and in vivo success. While it is understood that the absence of working examples should never be the sole reason for rejecting a claims as being broader than an enabling disclosure, the criticality of working examples in an unpredictable art, such as the prevention of a disease such as cancer, is required for practice of the claimed invention.

Quantity of experimentation

The quantity of experimentation in the areas of cancer prevention is extremely large given the fact that no known cure or preventive regimen is currently available for cancer.

The unpredictability of the art and the state of the prior art

The state of the art at the time of filing was such that one of skill could recognize that inhibition of TIPRAIP's such as HALP can be used as an effective method of treating cancer. For example, Bandman et al. teach (US 5,980,820, 1999) a method of treating cancer in a subject comprising administering an effective amount of an antagonist of HALP, eg. SEQ ID NO: 1 (column 3, lines 38-41). Bandman et al further teach that the antagonist of HALP can be used in a method of preventing cancer, but is silent on any model that would lead one of skill in the art to reasonably convey that the antagonist can be used in a method of preventing cancer. In the instant case, those of skill in the art recognize the prevention of cancer is highly unpredictable. For example, the majority of studies suggest that the essential element towards the validation of a preventive therapeutic is the ability to test the drug on subjects monitored in *advance* of clinical cancer and *link* those results with subsequent histological confirmation of the presence or absence of disease. Further, such studies require the appropriate experimental models for analyzing chemo- or immunoprevention. For example, Granziero *et al.* (Eur. J. Immunol. 1999, 29:1127-1138) teach that many models are not suitable for testing immunotherapeutic approaches intended to cure cancer. They suggest that the optimal model (prostate cancer, in their case) would have spontaneous tumor development in its natural location (1st column, page 1128) wherein disease progression would closely resemble the progression of the particular type of cancer. Hence, depending on the type of model employed one could establish a reasonable link between antecedent drug and

subsequent knowledge of the prevention of the disease. Further, reasonable guidance with respect to correlating agents that prevent cancer may depend upon quantitative analysis from defined populations that have been successfully pre-screened and are predisposed to particular types of cancer. This type of data might be derived from widespread genetic analysis, cancer clusters, or family histories. For example, Byers, T. (CA Journal, Vol. 49, No. 6, Nov/Dec. 1999) teaches that randomized controlled trials are commonly regarded as the definitive study for proving causality (1st col., p.358), and that in controlled trials the random assignment of subjects to the intervention eliminates the problems of dietary recalls and controls the effects of both known and unknown confounding factors. Further, Byers suggests that chemo-preventative trials be designed "long-term" such that testing occurs over many years (2nd col., p. 359).

Moreover, treatment of cancer in general is at most unpredictable, as underscored by Gura (Science, v278, 1997, pp.1041-1042) who discusses the potential shortcomings of potential anti-cancer agents including extrapolating from in-vitro to in-vivo protocols, the problems of drug testing in knockout mice, and problems associated with clonogenic assays. Indeed, since formal screening began in 1955, thousands of drugs have shown activity in either cell or animal models, but only 39 that are used exclusively for chemotherapy, as opposed to supportive care, have won approval from the FDA (page 1041, 1st column) wherein the fundamental problem in drug discovery for cancer is that the model systems are not predictive.

Conclusion

Thus given the broad claims in an art whose nature is identified as unpredictable, the specification being devoid of any models or experimental analysis that reasonably suggests that the claimed method would predictably prevent the formation of tumors in a mammal, combined with the state of the art of preventing cancer, it is the position of the examiner that it would require undue experimentation for one of skill in the art to perform the method of the claim as written.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Bandman et al. (US 5,989,820, 1999).

Bandman et al. teach a method of treating cancer in a subject comprising administering an effective amount of an antagonist of HALP, eg. SEQ ID NO: 1 (column 3, lines 38-41). With regards to the antagonist, the patent teaches that antagonists refer to molecules which when bound to HALP, decrease the amount or duration of the effect of the biological or immunological activity of HALP; and include, but are not limited to, proteins, nucleic acids, carbohydrates, antibodies or any other molecule which decrease the effect of HALP (column 5, lines 29-34), wherein the antagonist specifically bind HALP and can be identified by determining whether the antagonist binds specifically to HALP (column 18, lines 54-58). With regard to the cancer, the patent teaches that the cancer includes, but is not limited to adenocarcinoma, leukemia, brain or breast cancer (column 18, lines 24-33). Thus, while Bandman *et al.* do not characterize the HALP polypeptide described in the patent as SEQ ID NO: 1 as a Tail Interacting Protein Related Apoptosis Inducing Protein (TIPRAIP), the claimed limitation does not appear to result in a manipulative difference in the method steps when compared to the prior art disclosure because the specification teaches that (page 54, paragraph 0135) that non-limiting examples of TIPRAIPs include Sequence 1 from US Patent 5,989,820. Thus, the claimed peptide appears to be the same as the prior art. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed protein. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989). Moreover, even though the claims

are drawn to a mechanism by which the compound induces activation of the caspase cascade and further, induces apoptosis, the claimed method does not appear to distinguish over the prior art teaching of the same or nearly the same method. The mechanism of action does not have a bearing on the patentability of the invention if the invention was already known or obvious. Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention. In re Wiseman, 201 USPQ 658 (CCPA 1979). Granting a patent on the discovery of an unknown but inherent function would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art. In re Baxter Travenol Labs, 21 USPQ2d 1281 (Fed. Cir. 1991). See M.P.E.P. 2145.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Mao et al. (CN 1333292, 2001, abs) teach a human tail interacting protein TIP47, as well as method of treating various kinds of disease including, but not limited to cancer. The reference further teaches antagonist to said tail interacting protein and methods of therapy.

Therefore, NO claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J. Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached on Monday through Friday from 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brandon J Fetterolf, PhD
Examiner
Art Unit 1642

BF
June 13, 2006

JEFFREY SIEW
SUPERVISORY PATENT EXAMINER